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Can Judge Dan Polster Get Big Pharma to Pony Up Billions for Its Role in the Opioid Crisis?

By Daniel McGraw

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America will turn its drug-addicted eyes to Cleveland over the next year or two as the city becomes the capital of drug overdose law.

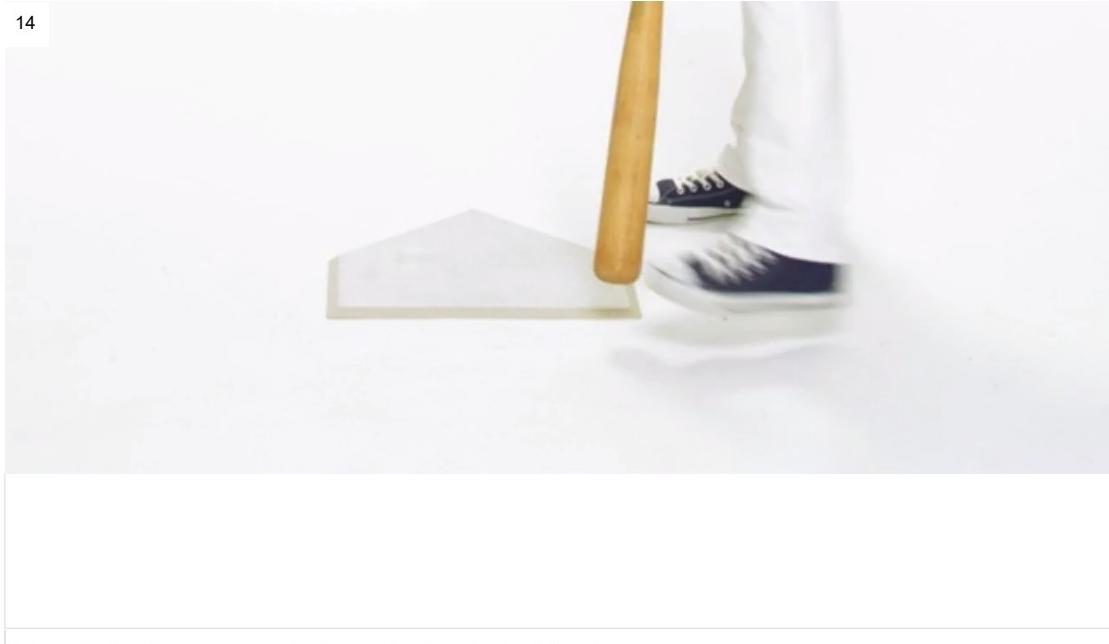
What has happened is pretty simple if we take the lawyering talk out of it. Cities, counties and states have gotten pissed off in recent years with skyrocketing prescription pain

medical usage and its ensuing public health crisis, thanks to overuses from prescribed and illegal opioids, which they've had to clean up, literally, figuratively and financially. That includes more crime, ambulances, processing dead bodies that pile up so quickly and in such great numbers that some county coroners have had to call in mobile trailers to accommodate the cadavers, more foster care, health care, and it goes on and on.

They asked the federal government for money to help, asked the FDA to restrict pain pills like OxyContin from being passed out like candy, asked the pharmaceutical companies to quit being so greedy, and even asked medical schools to teach their doctors not to prescribe so many.

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No one listened. And the stats kept getting worse.

The country now averages 52,000 overdose deaths a year. That's six an hour. If you are keeping score for Ohio, about 13 will die today from an OD. In Cuyahoga County, about two a day. For further perspective, those 52,000 who died from opioid-related overdoses nationally in 2016 were more than the deaths from breast cancer (40,000), car crashes (38,000), suicides (32,000), and homicides (17,000) that year.

So they all sued. Well, most of them. Nearly 400 cities, counties, states and Native American tribes (at last count) have filed lawsuits against opioid pill manufacturers and the companies that distribute them to pharmacies alleging the companies up and down the supply chain willfully produced, marketed and shipped astounding quantities of what they knew to be highly addictive drugs.

Those lawsuits might be put to rest at 801 Superior Ave. on the 18th floor of the Carl B. Stokes Federal Courthouse.

In December 2017, the U.S court system brought all those cases together in what's known as a Multi-District Litigation (MDL). Basically, the process gathers a whole bunch of similar cases and streamlines them through one court after which they'd all share rulings — what documents the defendants need to provide, who must sit for depositions, rulings on various motions and evidence — and then the cases return to the state where they were initially filed for actual trial.

The judicial panel chose Cleveland, and federal Judge Dan Polster, for the MDL. For a variety of reasons. Cleveland has been among the hardest hit areas of the country, for starters, and many of the cases filed come from neighboring states.

Kicking the cases back to trial is one option for how this can work. In reality, judges in MDL cases have all sorts of latitude and leeway, and some figure they can take the bull by the horns, tell the high-priced lawyers to go sit in a corner, and craft some master settlement for all the cases at once. That's what's happening in Cleveland with Polster, a Shaker Heights native and Clinton appointee, who has indicated he wants to be the kind of MDL judge who does more than play legal traffic cop. That much was clear from the start, and perhaps not surprising given Polster's reputation and advocacy for settlements in lieu of expensive and lengthy trials.

At the first meeting of the major players in his courtroom on Jan. 9, when Polster told them to immediately begin getting ready for settlement talks, he said a pretty amazing thing to the lawyers involved, indicating that everyone's to blame, and that any settlement had to go beyond dollars and cents to address real, viable solutions to a problem that is decimating the American population.

"This is not a traditional [case]," he said. "What's happening in our country with the opioid crisis is present and ongoing. I did a little math. Since we're losing more than 50,000 of our citizens every year, about 150 Americans are going to die today, just today, while we're meeting.

"And in my humble opinion, everyone shares some of the responsibility, and no one has done enough to abate it. That includes the manufacturers, the distributors, the pharmacies, the doctors, the federal government and state government, local governments, hospitals, third-party payers, and individuals. The federal court is probably the least likely branch of government to try and tackle this, but candidly, the other branches of government, federal and state, have punted. So it's here.

"So I don't think anyone in the country is interested in a whole lot of finger-pointing at this point, and I'm not either. Just dramatically reduce the quantity, and make sure that the pills that are manufactured and distributed go to the right people and no one else, and that there be an effective system in place to monitor the delivery and distribution. Because sadly, every day more and more people are being addicted, and they need treatment."

That was not a traffic-cop judge speaking. Indeed, he quickly drew criticisms from lawyers involved — The New York Times, while shadowing him for a day, overheard counsel calling him a "grandstander" and "Pollyanna" — and from the legal community at-large keenly following the proceedings. One Yale law professor remarked, "To say his goals are ambitious would be an enormous understatement."

Polster, 66, who the Times noted had a hasty lunch of a hard-boiled egg and a tangerine that day, had no qualms concurring with the sentiment. "I think that's a fair assessment," he told the paper. "But I won't fault myself for attempting this."

"This" is presiding over a case which represents the interests of the medical community, political policy, deaths that are hitting every age and gender and race in every state, big pharma power, and multi-billions of dollars that could be dispersed to little towns around the country.

And he might have to settle this by telling millions of Americans that they can't have as many pain pills as they used to, that pain is more of symptom and not a disease as some have pushed.

No one knows how this hearing can, if not quixotic, journey might turn but, but no judge in recent times has ever really tried to handle something this monstrous. This is a historic crisis, and it's happened on our collective watch.

"I read recently that we've managed in the last two years, because of the opioid problem, to do what our country has not done in 50 years, which is — for two consecutive years — to reduce, lower the average life expectancy of Americans," Polster said at the January hearing. "And if we don't do something in 2018, we'll have accomplished it for three years in a row, which we haven't done since the flu epidemic 100 years ago wiped out 10 percent of our population. And this is 100-percent manmade. Now, I'm pretty ashamed that this has occurred while I've been around. So I think we all should be."

Michael Moffitt is a Harvard Law School professor specializing in negotiations, dispute resolution and mediation in civil cases like this. He's from Wadsworth and lived in Avon Lake some years ago while clerking for federal judge Ann Aldrich in Cleveland.

When asked how Polster might act in a case like this, he did what most do, throwing up his hands and declaring, "Who knows?" But Moffitt does see something different happening.

"For about a decade, I used to teach civil procedure: a required, introductory course for all first-year law students, aimed at helping them to understand the basic rules, concepts, and structures of modern litigation," Moffitt said. "Inevitably, at some point during the year, a student would raise her hand and ask, 'Can a federal district court judge ... , and I would cut her off, responding, 'Yes.' The class would laugh, and I would explain that it's hard to finish that question in a way that would make me wrong.

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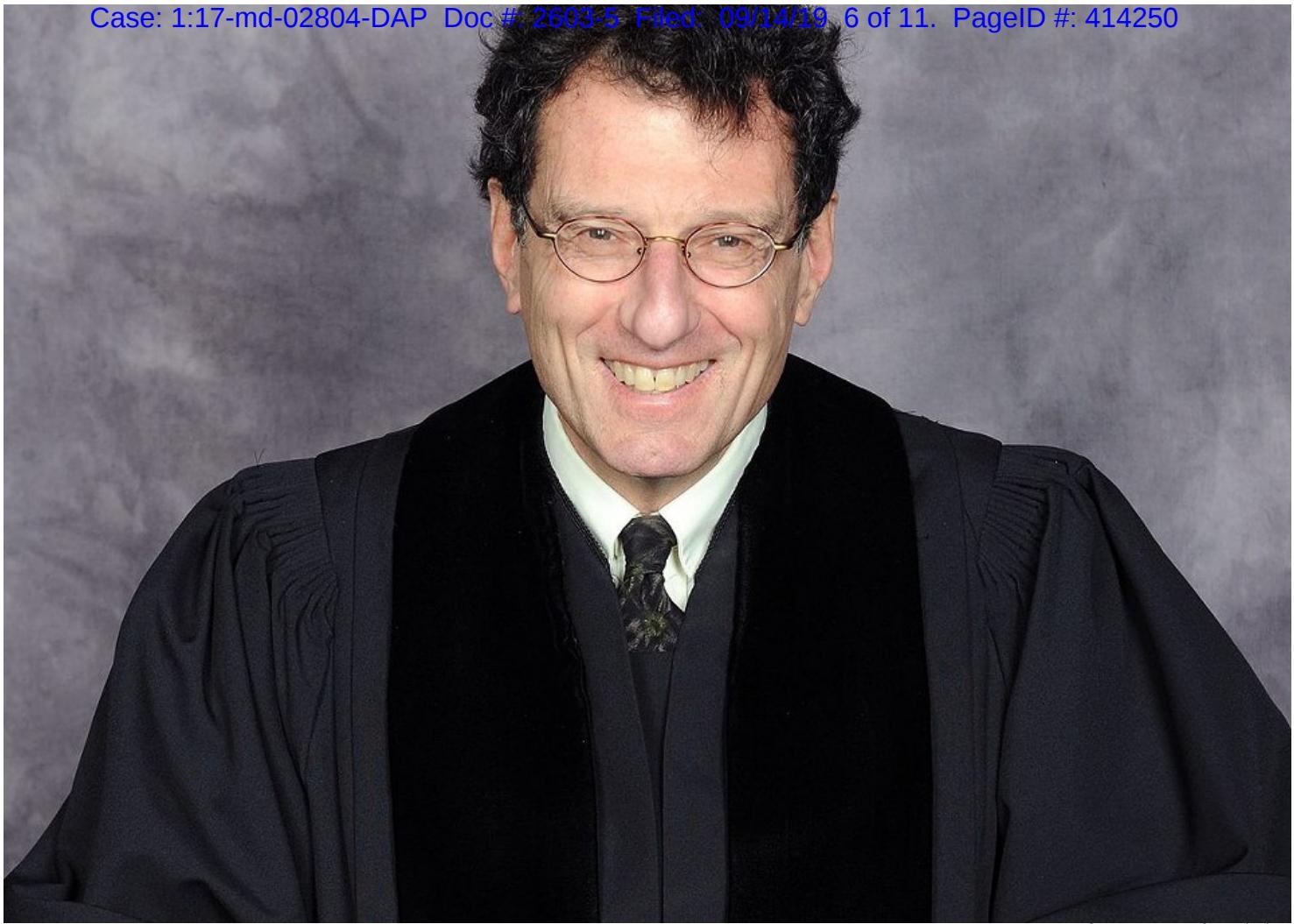


Photo courtesy Northern District C

Federal judge Dan Polster

"I know that reading judicial tea leaves is something of a sport, both among academics and among members of the practicing bar. My admittedly uncomplicated, perhaps unsophisticated, inclination in this case would be to believe that Judge Polster means what he said on Jan. 9.

"The prominence of discretion, the opportunity for creative problem solving, and the lack of narrow constraints on the judge or on the parties are precisely what causes some to be nervous and some to be optimistic," Moffitt continued. "But regardless of one's initial reaction to the conversations that are beginning in Ohio, we should all be curious, because we are all likely to be affected by what emerges — or doesn't emerge."

Polster's background would lead many to believe he will be trying to run down a path few would try. A native and current resident of Shaker Heights, and a member of the Jewish congregation Shaarey Tikvah in Beachwood and Park Synagogue in Cleveland Heights and Pepper Pike, he often cites the Old Testament Deuteronomy passage, "Justice, justice, you shall pursue," as influencing how he manages his court.

He is keeping a low profile in this case, and has instructed the lawyers and politicians involved in this case not to divulge any settlement discussions to the media. He himself is abiding by those restrictions. But reading the tea leaves of his Cleveland upbringing, there's enough of a varied cultural and political mix to make "creative problem solving" a possibility for him.

He grew up in the Ludlow neighborhood in Cleveland in the 1950s, just off Shaker Square, and his parents helped form a neighborhood association that discouraged the "redlining" and

In a 2016 interview with The Federalist Lawyer about his parents' action, Polster said,

"Ordinary people can do extraordinary, heroic things if they recognize the opportunity and realize, 'This is my time to do something significant, I'm not going to take a pass.' Usually people take a pass."

In grade school, his Little League baseball coach was Cleveland Indians' third baseman Al Rosen (whose son was on the team).

Rosen, "The Hebrew Hammer" who tended the hot corner for the Indians for 10 years and won an AL MVP in 1953, tried to teach the sixth-grader how to hit a curveball. Polster couldn't figure the curve out, went home one day, threw his glove on the floor, and told his parents, "I guess I gotta be a lawyer."

He graduated from Shaker Heights High School in 1969, starring there as a cross-country runner, elected council member, and sports editor of the school newspaper, before heading to Harvard College and Law School. At age 66, he still runs often and is known to bicycle long distances throughout the east side of Cleveland. He's also been a volunteer reading instructor for the Cleveland Municipal School District and the Jewish Community Federation, and is known to keep a schedule packed from morning to night.

He was appointed as federal judge by former President Bill Clinton in 1998, but his first legal experience was not so liberal: One of his early jobs after law school was with the U.S. Department of Justice, a post he secured after he impressed his interviewer, future Supreme Court justice and conservative legal giant Antonin Scalia.

He has been married for more than 40 years to fellow Cleveland lawyer Deborah Coleman (she being an expert in antitrust, intellectual property and technology) and they have three adult kids. Those who know him say he is seen quite often at Browns, Cavs and Indians games.

He is known for two completely different news items in recent years. The first was his handling of the breakaway Amish sect case where the charges of shaving men's beards against their will was filed under the new hate crimes law. Polster sentenced the bishop of that sect, Samuel Mullet, to 15 years in jail (since reduced to 10 years).

Polster said his challenge was not allowing the oddness of an Amish hate crime case — along with the accused being a beard-cutter ironically named "Mullet" — to become a media spectacle. "I am very glad I had that case in my 15th year as a judge," he told The Federalist Lawyer. "I couldn't have handled it very well as a rookie judge."

His other recent appearance in the headlines came about a year ago. Polster spoke out against President Donald Trump after the president derided a judge who ruled Trump's Muslim travel ban unconstitutional. Trump called that judge a "so-called judge."

"This is serious business, because you start calling into question the legitimacy of someone, that undermines the whole system, all right?" Polster said at a private meeting in Bratenahl last February, as reported by Cleveland.com, to a small group that included suburban mayors, attorneys and city officials.

I think to say it publicly, that's his right. But it gets into question, and some might even say forfeits, his or her own legitimacy. So I'll leave it at that. It's an important question, but that's how I feel ... I don't believe there's a single federal judge who would be intimidated by anybody. We took an oath to support and defend the Constitution and it means a lot. And I think that oath means even more today."

The power Polster has in this big case is not lost on the Cleveland legal community. There are already more than 200 lawyers listed in the filings, and the big companies are loading up on local Cleveland legal talent to help skew any possible settlement decision their way. "What can happen in [this case] is likely going to result in public policy changes on the federal and state levels," said Lee Fisher, dean and professor of law at Cleveland-Marshall College of Law.

And one lawyer said doing what Polster has taken on — trying to balance settlement money with public policy changes — will be very difficult to accomplish. But he says Polster might be capable of doing it better than most, in that he knows how to keep all sides in line.

"A lot of the plaintiffs in these cases — the local and state government agencies — will try to turn this into a punitive damages case to get their public government agencies some money to pay off their expenses from all these overdoses," said one Cleveland lawyer who has tried cases before Polster, but who didn't want his name used. "Think of it this way: How much does it take to punish a big pharmaceutical company that builds these costs into their business plan to survive the long haul? But how will the evidence work that the medical and pharmaceutical profession likely created a culture of pain pills that are addictive and don't do much for pain anyway."

"The defense might be that the maker of OxyContin gave America what it wanted, and the FDA and the doctors and the many researchers signed off on this," he said. "We are now a pill society. People are in pain. They get pills prescribed for their pain because they really want those pills. How do you blame the pill makers alone for all this? That's what Judge Polster has to deal with."

And that raises all sorts of legal questions. Some are comparing the Cleveland MDL opioid litigation to the Big Tobacco settlement of 1998. The cigarette companies agreed to pay about \$206 billion to the states over the first 25 years. As Mississippi attorney general Mike Moore said back then, "[The] lawsuit is premised on a simple notion: You caused the health crisis; you pay for it."

Are there legal similarities between cigarette sales in a convenience store and an opioid prescription from a doctor?

"The public went against the cigarette companies back in the '90s because they were seen as the villains in all this, and that's probably why the settlement amount got so high," said Browne C. Lewis, director of the Center for Health Law and Policy at the CSU law school. "But I'm not sure the public will want to make the medical community villains in all this like they did tobacco. It's a very slippery slope. The pain component of this will be difficult to figure out. They will say their intentions were good in some respects, and they wanted to alleviate pain. And they will have all sorts of examples of people where they did alleviate the pain."

"So it might come down to the settlement being a change in public health care policy," Lewis said. "Like how we approve pharmaceutical medications and how we oversee prescriptions. How the money fits in will be the hard part to figure out."

A few years ago, I interviewed a retired surgeon, now in charge of a residency program at a large medical school, who goes by "Skeptical Scalpel" in his blog. "People are more acclimated to getting medication for anything now, and they expect it," Scalpel said. "Millennials have been overmedicated since they were born. They say they are depressed, and instead of figuring out why, we give them a prescription for Zoloft. ... It's all part of the pill medicalization of the entire country."

Over the years, demands on doctors have grown. They were now seeing three patients an hour and often had no time to figure out who needs what pain meds and for how many days or months. "What has happened is that we have created a culture where the pain medication is not only expected, it is demanded by the patients."

Parma mayor Tim DeGeeter sees things a little differently. In 2012, his Cleveland suburb, which is also the seventh largest city in Ohio, had no drug overdose deaths. By 2016, it had 20. And those are just the deaths, not the countless victims who overdosed and survived.

"The cities are at ground zero in dealing with this," DeGeeter said. "In 2017, we had to provide overdose help to 136 males, and 64 females in Parma. The youngest was 19, the oldest was 63. These were people who were employed, unemployed, with college degrees, high school grads, it knows no boundaries or group that it settles in. And nothing is getting done in Washington on this."

"For me as mayor of a city suffering from this, I would be remiss if we did not file a lawsuit on this situation on behalf of our citizens who are paying for this in so many ways," he continued. "We aren't expecting a great windfall, but we are expecting a knock on our door with someone there to say we have settled this and we're here to help and we'll have less people dying in your city."

Who's knocking though, and who's cutting the check? That's another complicated question in an already complicated situation. Say someone was prescribed OxyContin and, over time, became addicted and overdoses. Who gets the blame?

Purdue Pharma, which makes OxyContin, is being sued for possibly lying to doctors about the addictive nature of the medicine. (In what many in the legal community say is an acquiescence to Polster, a gesture of sorts, Purdue last month announced it would cease marketing OxyContin to doctors.) Cardinal Health, a prescription distributor based in Dublin, Ohio, is said to be at fault as well, for dumping alarming amounts of painkillers around the country. And then there's CVS and Walgreens and all the other pharmacies that are alleged to have ignored red flags as they bottled billions of dollars of the medications.

The lawsuits argue that anyone who touched that pill before you ingested it, ground it up and shot it into your arm or snorted it could be said to be liable. The defendants, however, claim they were providing a legal, federally approved prescription. Whatever the individuals did, they did themselves.

The U.S. Drug Enforcement Agency keeps data on all prescriptions, who dispenses the meds to whom, what was dispensed and how much. The plaintiffs wanted about 10 years' worth of that data; the DEA said that would be a problem. The agency argued it would be "law enforcement sensitive," meaning the Feds feared illegal drug dealers could use the records to target users; but Polster ruled the DEA must turn it over, though the info won't be shared with the public.

If what we already know about the massive, mindboggling quantities of painkillers shipped to West Virginia is any indication, the numbers Polster looks at for the rest of the country are likely to poke holes in the defendants' case. A Pulitzer Prize-winning investigation from the West Virginia Gazette revealed wholesale pharmaceutical companies flooded Kermit, an old

coal-mining town on the Tug River with a population of 400, with 12 million opioid pills between 2007 and 2012, or about 30,000 pills for every resident.

In total, 780 million opioid pills were shipped to the state over that span, or 433 for every West Virginian.

Hard data is good, but it opens more questions. Not of who's to blame — it's clear by now the answer to that is everyone involved — but to what degree. How much of this was America's thirst for pharmaceuticals? How much was deceit on the part of Big Pharma? How much do we blame the medical community? How much was it a failure of those charged with overseeing public health?

Say Polster gets the sides to agree to a settlement. The first question, of course, is how much money will go to the plaintiffs. The second question is how they would be able to use it.

The major criticism of the 1998 \$250 billion Big Tobacco settlement between the cigarette makers and 45 states was the fact that the settlement — payable over 25 years — gave no stipulations on how the states might spend that money. Many used a small portion of the funds for tobacco control and cessation programs, but most of the dough was typically used for other purposes, such as security for loans or simply for a state's general fund.

Ohio sold its future collections from the settlement for \$5 billion in a bond sale (estimates say it could have collected more than three times that amount if it hadn't) and used the cash for a variety of things, including paying down debt, giving real estate tax breaks to seniors, funding construction of schools, and spending \$20 million to make E-Checks free for all residents.

No states provided for direct payments from the settlement to individuals, to pay for medical costs resulting from tobacco use.

The national smoking rate has fallen to historic lows since that settlement, with just 15 percent of adults still smoking. But the gap between the number of less-educated rural smokers and the more-educated urban smokers is higher than ever: Researchers have found that America's lower class now smokes more and dies more from cigarettes than other Americans.

And again, that underscores the problems with these MDL opioid cases. Is a judge in Cleveland going to be able to rein in opioid addictions nationally, including in small towns in West Virginia? And if the opioid makers and distributors figure that a big multi-billion dollar settlement is just the cost of doing business, will the cities and counties that get big money use it to reduce addiction in the communities or to repair sidewalks and pave streets?

Oh, and the feds might want in on this as well. In November, Pres. Trump's Council of Economic Advisers estimated that the opioid drug epidemic cost the country \$504 billion in 2015, in terms of lost lives, lost productivity, health care, treatment, criminal justice and other costs. If the cities, counties and states are getting theirs, one expert told me, the feds will want to drink from that trough too.

Purdue's announcement that it would end OxyContin marketing was a small but tangible sign things are heading in a productive direction. And lawyers remarked to various media following the first settlement conference in January that they were cautiously optimistic after their initial reticence in the face of Polster's bold direction.

"The parties reported important and substantial progress on several fronts, but also identified various barriers to a global resolution," the judge wrote in a filing after a March 6 meeting. To address some of those barriers, Polster said they agreed to use a "limited litigation track," which basically means a few of the lawsuits may go forward with discovery, motions and trials in what amounts to test balloons so each side can get a feel for how a judge and jury view their cases. He's asked for a plan to be submitted by March 16.

The next settlement conference is scheduled for May 10.

Hundreds more will die between then and now, and hundreds if not thousands more will die between May 10 and whenever a settlement might be reached. Maybe Polster really is overly ambitious in thinking he can wrangle a solution that will shrink those numbers one day, but it certainly won't hurt to try.

"The judicial branch typically doesn't fix social problems, which is why I'm somewhat uncomfortable doing this," he told the Times. "But it seems the most human thing to do."

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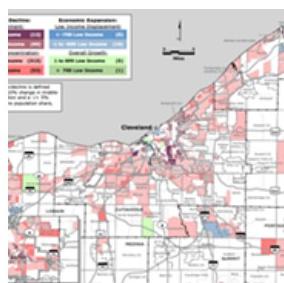
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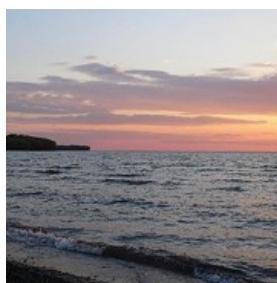
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